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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,577	10/23/2003	Insu Lee	59150-8011.US01	9013

22918 7590 09/07/2007

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,577	LEE ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-12 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *15 June 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on June 15, 2007 is acknowledged.

Status of the Claims

1. Claims 4-12 and 22-24 are pending in the application. The new claims 22-24 were added in an "Amendment – After Non-Final Rejection" filed on June 15, 2007. Accordingly, claims 4-12 and 22-24 are being examined on the merits herein.

Information Disclosure Statement

The Information Disclosure Statement submitted on June 15, 2007 is acknowledged.

Response to Arguments

2. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on June 15, 2007, with respect to "Rejections under 35 U.S.C. § 112, 1st paragraph" to claims 4-12 have been fully considered and are persuasive in part. Claim 4 has been amended to remove the term "brain function" and including the term "learning faculty. Furthermore, new claim 22 is directed to a method of "improving memory. However, new claims 23-24 are directed to methods of improving "recognition ability" and improving "visual identification", respectively and are the subject of a new ground(s) of rejection under 35 U.S.C. § 112, 1st paragraph. Thus, the Rejections under 35 U.S.C. § 112, 1st paragraph to claims 4-12 have been withdrawn in light of the amendments.

3. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on June 15, 2007, with respect to "Rejections under 35 U.S.C. § 102" to claims 4-7, and 10 has been fully considered and are persuasive. The references Spinner et al. (US 4,948,811) as evidenced by Rehkämper et al. (Journal of Dairy Science, 1998, vol. 81, pp. 1574-1580) do not teach visual identification but rather visual acuity and that visual acuity and visual identification are not synonymous. However, Rehkämper et al. disclose their method of testing visual acuity in cattle (abstract). In the experiments of Rehkämper et al., the adult dairy bulls wee trained to recognize a black disk and then to differentiate between the black disk and a black annulus with a white center (abstract). Accordingly, one must be able to visually identify what the object is in order to be able to distinguish between different objects. As such, visual acuity cannot take place without visual identification. Thus, visual identification is generic to visual acuity and that improvement to visual acuity certainly leads to an improvement to visual identification. It would be obvious, rather than inherent, that visual acuity cannot exist without visual identification. Thus, the Rejections under 35 U.S.C. § 102 to claims 4-7, and 10 have been withdrawn in light of the arguments.

4. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on June 15, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 4-12 has been fully considered and are persuasive in part. The reference Stordy (US 6,150,411) teaches a method of treating dyslexia comprising administering DHA. Dyslexia is a disorder manifested by difficulty in learning to read. The method of Stordy does improve learning, albeit the learning is specifically focused on reading. Learning in general would then be obvious using Stordy which teaches improving learning to read. The reference Rehkämper et al. (Journal of Dairy Science,

1998, vol. 81, pp. 1574-1580) disclose their method of testing visual acuity in cattle (abstract). In the experiments of Rehkämper et al., the adult dairy bulls wee trained to recognize a black disk and then to differentiate between the black disk and a black annulus with a white center (abstract). Accordingly, one must be able to visually identify what the object is in order to be able to distinguish between different objects. As such, visual acuity cannot take place without visual identification. It would be obvious that visual acuity cannot exist without visual identification.Thus, the Rejections under 35 U.S.C. § 103 to claims 4-12 stand rejected under Stordy.

5. Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection. The following new ground(s) of rejection to amended claims 4-12 and new claims 22-24 are used herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for strengthening learning faculty and improving memory, does not reasonably provide enablement for improving recognition ability and visual identification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan

to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to a method of stengthening learning faculty, improving memory, improving recognition ability, and improving visual identification.

(2). ***State of the Prior Art***:

The skilled artisan would use docosahexaenoic acid (DHA) since DHA has been shown to play an important role in visual identification, recognition ability, learning faculty, and memory.

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the art of DHA is extremely high.

(4). ***Predictability of the Art***:

DHA is also involved in the synthesis of cholesterol, blood clotting inhibition, aging, and cancer and is beneficial for the treatment of cardiovascular aliments, arthritis rheumatica and asthma and other lung diseases (page 1, paragraphs 2-3). Thus, the effects of DHA are highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the administration of linoleic acid and α-linolenic acid, the fatty acids from which DHA is derived, at various ratios of linoleic acid to α-linolenic acid to stengthen learning faculty, improve memory, improve recognition ability, and improve visual identification.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to improve recognition and improve visual identification by administering linoleic acid and α-linolenic acid at various ratios of linoleic acid to α-linolenic acid is limited.

The disclosure of stengthening learning ability and memory retention ability by

administering linoleic acid and α-linolenic acid at various ratios of linoleic acid to α-linolenic acid is adequate (pages 7-10).

(7). ***Working Examples***:

Rats were administered linoleic acid and α-linolenic acid at various ratios of linoleic acid to α-linolenic acid and then subjected to the Morris maze test to access learning ability and memory retention ability (page 7). The results show the shorter the retention time, the higher the learning ability for a linoleic acid to α-linolenic acid ratio of 2 (figure 3A and B). The results also show the shorter the retention time, the higher the memory retention ability for a linoleic acid to α-linolenic acid ratio of 2 (figure 4A and B). Thus, the working examples show how to strengthen learning ability and memory retention ability, not how to improve recognition and visual identification.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support of improving recognition and improving visual identification by administering linoleic acid and α-linolenic acid. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any drugs having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the

art would not be able to fully practice the instant invention without ***undue experimentation***.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 5-12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinner et al. (4,948,811) as evidenced by Rehkämper et al. (Journal of Dairy Science, 1998, vol. 81, pp. 1574-1580).

Spinner et al. teach triglyceride cooking/salad oil composition that can be used to promote growth and improve the development of visual acuity in humans and animals, wherein the composition is made up of linoleic and α-linolenic fatty acids in a weight ratio of linoleic and α-linolenic fatty acids at 2.0 (abstract; column 3, lines 5-7; column 4, lines 9-12; and column 4, lines 22-23).

Spinner et al. do not specifically teach visual identification but they teach a composition that includes linoleic and α-linolenic fatty acids that is used to promote growth and improve the development of visual acuity.

As evidenced by Rehkämper et al. visual acuity is defined as the minimum size of an identifiable object (page 1574). Rehkämper et al. disclose their method of testing visual acuity in cattle (abstract). In the experiments of Rehkämper et al., the adult dairy bulls wee trained to recognize a black disk and then to differentiate between the black disk and a black annulus with

a white center (abstract). Accordingly, one must be able to visually identify what the object is in order to be able to distinguish between different objects. As such, visual acuity cannot take place without visual identification. Thus, it would obvious that such a composition to improve visual acuity can also improve visual identification as recited in instant claim 24.

Regarding the composition added to food as recited in instant claims 11-12, it is noted that Spinner et al. teach triglyceride cooking/salad oil composition that is made up of linoleic and α-linolenic fatty acids, which closely meets the amounts of a daily dose set forth in instant claims 11-12 (abstract; column 3, lines 5-7; column 4, lines 9-12; and column 4, lines 22-23). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of linoleic and α-linolenic fatty acids provided in a composition, according to the guidance set forth in Spinner et al., to provide a composition having the desired amount of linoleic and α-linolenic fatty acids. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

8. Claims 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stordy (6,150,411).

Stordy teaches a method of treating dyslexia comprising administering a DHA composition (column 2, lines 31-34). The DHA composition further comprises linoleic and α-linolenic fatty acids (column 4, lines 18-20). It is noted, Stordy teaches that dyslexia is a disorder manifested by difficulty in learning to read (column 1, lines 8-9). As such, the method

of Stordy teaches an improvement of learning, albeit learning to read. Thus, it would be obvious that Stordy teaches a method to improve learning as recited in instant claim 4.

Stordy also teaches that the daily dose of DHA is 20 mg to 10 g to children or adults (column 3, lines 22-23).

Additionally, Stordy teaches that for salad oils or for incorporation into any appropriate food material contain 5% by weight DHA (column 3, lines 28-30).

Regarding the daily dose of the composition, as recited in instant claims 8-9, it is noted that Stordy teach providing the DHA composition, a composition that contains linoleic and α-linolenic fatty acids, at 2 mg to 10 g, which closely meets the amounts of a daily dose set forth in instant claims 8-9. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of DHA provided in a composition, according to the guidance set forth in Stordy, to provide a composition having desired daily dose. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

9. Claims 4-12 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yehuda (US 5,120,763) in view of Riekkinen et al. (Brain Research, 1996, Vol. 714, pp. 118-124).

Yehuda teaches a method for memory enhancement in mammals, including humans, comprising administering a composition of about 13 to about 27.5% of a derivative of linolenic acid and about 87 to about 72.5% of linoleic acid (abstract). The composition of Yehuda is a

pharmaceutical composition or a nutritional composition (abstract). It would be obvious that the derivative of linolenic acid can be α-linolenic acid.

Yehuda does not teach learning enhancement.

Riekkinen et al. teach a method of improving memory comprising administering α-linolenic acid and linoleic acid in a 1:4 ratio (abstract). The test Reikkinen et al. used to evaluate the compound for memory improvement employs the water maze (WM) and passive avoidance (PA) test, which is a well known pharmacological model to test learning behavior (abstract and page 118). Thus, a compound that is evaluated for memory improvement using the WM and PA test is also evaluated for learning behavior. Accordingly, it would be obvious that the method for memory improvement of Riekkinen et al. also applies to learning.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the α-linolenic acid and linoleic acid composition of Yehuda to treat learning and memory because the compounds of Riekkinen et al. teach an α-linolenic acid and linoleic acid composition and according to Riekkinen et al., α-linolenic acid and linoleic acid improves memory and learning.

The motivation to combine the α-linolenic acid and linoleic acid compound of Yehuda to the α-linolenic acid and linoleic acid compound of Riekkinen et al. is that the α-linolenic acid and linoleic acid compound of Riekkinen et al. can be used to improve memory and learning.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third

composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Recognition and visual identification are processes that involve memory and learning behaviors. After all, one cannot recognize or visually identify an object with first learning the physical characteristics of that object. Recognition and visual identification further requires that one must be able to remember the physical characteristics of that object. Thus it would be obvious that a method to improve memory and learning includes improving recognition and visual identification.

Regarding the ratio of α-linolenic acid and linoleic acid as recited in instant claims 4 and 22-24, the composition of Yehuda comprises about 13 to about 27.5% of a derivative of linolenic acid and about 87 to about 72.5% of linoleic acid, which closely meets the ratio of linoleic acid to α-linolenic acid set forth in instant claims 4 and 22-24 (abstract). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of α-linolenic acid and linoleic acid provided in a composition, according to the guidance set forth in Yehuda, to provide a composition having desired ratio of linoleic acid to α-linolenic acid. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the daily dose of α-linolenic acid and linoleic acid in the composition, as recited in instant claims 8-9, the composition of Yehuda comprises about 13 to about 27.5% of a derivative of linolenic acid and about 87 to about 72.5% of linoleic acid, which closely meets the amounts of a daily dose set forth in instant claims 4 and 22-24 (abstract). It is considered that

one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the daily does of α-linolenic acid and linoleic acid provided in a composition, according to the guidance set forth in Yehuda, to provide a composition having desired daily dose. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the composition is an amount of the total food weight as recited in instant claims 11-12, Yehuda teaches the α-linolenic acid and linoleic acid composition is in a pharmaceutical composition or a nutritional composition, which closely meets the amounts of an α-linolenic acid and linoleic acid composition in food set forth in instant claims 11-12 (abstract). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of α-linolenic acid and linoleic acid in food provided in a composition, according to the guidance set forth in Yehuda, to provide a composition having the desired amount of the α-linolenic acid and linoleic acid composition in food. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Conclusion

10. No claims are allowable.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Wang

SHENGJUN WANG
PRIMARY EXAMINER

ckh